

**REMARKS**

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks herein.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1-6, 9-11, 26, 28, 30 and 32 are now pending. Claims 7, 8, 12-25, 27, 29, 31, and 33 are cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Applicants specifically reserve the right to pursue the cancelled subject matter in a subsequent divisional or continuation application..

No new matter is added.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled..

**II. THE DOUBLE PATENTING REJECTION IS OVERCOME**

Claims 1-6, 9-11, 26, 28, 30, and 32 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-9 and 18-30 of U.S. Patent No. 5,955,077. The rejection is respectfully traversed.

Submitted herewith is a Terminal Disclaimer. Consequently, reconsideration and withdrawal of the rejection is respectfully requested.

**III. TERMINAL DISCLAIMER**

Claims 1-6, 9-11, 26, 28, 30, and 32 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-9 and 18-30 of U.S. Patent No. 5,955,077 ("the '077 patent). For the purposes of expediting prosecution, without any admission, without any prejudice, without surrender of subject matter, without any intention of creating any estoppel as to equivalents, a Terminal Disclaimer as to the '077 patent is herewith provided herein:

I, Thomas J. Kowalski, declare that I am the attorney of record and that I am authorized to execute terminal disclaimers on behalf of Statens Serum Institut, the assignee of the above-

captioned application ("the present application") and U.S. Patent No. 5,955,077 ("the '077 patent");

That Statens Serum Institut has a place of business at Artillerivej 5, DK-2300 Copenhagen S, DENMARK;

That Statens Serum Institut is the assignee of the entire right, title and interest in, to and under U.S. Application Serial No. 09/804,980, filed March 13, 2001 (the present application) as a continuation-in-part of U.S. Application Serial No. 09/289,388, filed April 12, 1999, which is a continuation of U.S. Application Serial No. 08/465,640, filed June 5, 1995, now U.S. Patent No. 5,955,077, by virtue of the assignment from the inventors as set out at Reel 011892 and Frame 0354, where said assignment was recorded at the U.S. Patent and Trademark Office on June 11, 2001;

That the Statens Serum Institut is the assignee of the entire right, title and interest in, to and under U.S. Application Serial No. 08/465,640, filed June 5, 1995, now U.S. Patent No. 5,955,077 ("the '077 patent"), by virtue of the assignment from the inventors as set out at Reel 007630 and Frame 0343, where said assignment was recorded at the U.S. Patent and Trademark Office on August 31, 1995

That Statens Serum Institut hereby disclaims the terminal part of any patent granted on the present application which would extend beyond the expiration date of the full statutory term of the '077 patent;

That Statens Serum Institut hereby agrees that any patent so granted on the present application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to the '077 patent, this agreement to run with any patent granted on the present application and to be binding upon the grantee, its successors or assigns;

That no terminal part of any patent granted on the present application is disclaimed prior to the full statutory term of the '077 patent, in the event that said '077 patent earlier expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or is terminally disclaimed under 37 C.F.R. § 1.321(a), has all claims canceled by a reexamination certificate, or is otherwise terminated prior to expiration of its full statutory term, except for the separation of legal title stated above;

In accordance with 37 C.F.R. § 3.73(b), the undersigned attorney of record, empowered to sign this Statement on behalf of the assignee, states that the Statens Serum Institut, is the

assignee of the entire right, title and interest in the patent and patent application identified above (the present application and the '077 patent) by virtue of the assignment identified above.

And thus, that the undersigned has reviewed documents in the chain of title of the patent and patent application identified above and, to the best of the undersigned's knowledge and belief, title is in the assignee identified above.

Reconsideration and withdrawal of the double patenting rejection are respectfully requested; and, consideration and entry and recordal of this Terminal Disclaimer are also earnestly solicited, with any fee therefore or any overpayment in such fees, to be charged or credited to Deposit Account No. 50-0320.

#### **IV. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claims 1, 2, 4, 6, and 9-11 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the use of the phrase "substantially pure" is objected to.

And, claim 4 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the use of the phrase "derived" is objected to.

The rejections are respectfully traversed.

The fact that claim language includes terms of degree does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Indeed, contrary to the Office Action, MPEP 2173.05(b) permits the use of "substantially". "Substantially pure" is definite in view of the general guidelines contained in the specification, specifically on page 6, lines 13-20. The compositions of the present invention would not include other polypeptide materials except perhaps small amounts thereof as described in the specification.

Similarly, "derived" is also supported in view of the general guidance contained in the specification and by those of ordinary skill in the art. In claim 4, the polypeptide fragment is derived from a virulent mycobacterium or, in other words, one of ordinary skill in the art by reading the specification and common knowledge in the art would be able to obtain polypeptide fragments from a virulent mycobacterium.

Furthermore, a quick review of recently issued patents revealed the recited terms "substantially pure" and "derived" in the claims, for example, U.S. Patent No. 6,593,110 to Guo

et al. in which claim 1 reads: "An isolated polynucleotide encoding a substantially pure polypeptide as set forth in SEQ ID. NO: 2'." (Emphasis added). In addition, in the same patent, claims 5 and 6 recite expression vectors which are virus-derived and plasmid-derived, respectively. Another example is U.S. Patent No. 6,143,872 to Barbour et al. in which substantially pure polypeptide as well as Osp genes derived from strains of *B. burgdoferi* are claimed. Finally, it should be noted that the Examiner recently allowed claims in Patent Application 09/050,739, containing the objected claim language. (See claims 54-59).

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are respectfully requested.

### CONCLUSION

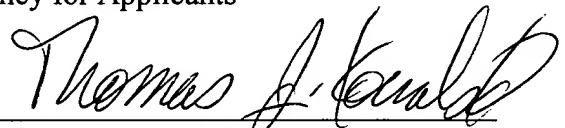
Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance. Prompt issuance of a Notice of Allowance is earnestly solicited.

The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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By: \_\_\_\_\_



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